

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 05814WO	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2005/006429	International filing date (day/month/year) 25.03.2005	Priority date (day/month/year) 25.03.2004	
International Patent Classification (IPC) or national classification and IPC G01N33/50, C12Q1/26			
Applicant FUENCE CO., LTD.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>	
Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. 1

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement	
Novelty (N)	Claims <u>1-8</u> YES Claims _____ NO
Inventive step (IS)	Claims _____ YES Claims <u>1-8</u> NO
Industrial applicability (IA)	Claims <u>1-8</u> YES Claims _____ NO
2. Citations and explanations (Rule 70.7)	
	<p>Document 1: JP 2002-520360 A (The Picower Institute for Medical Research), 09 July 2002, refer to paragraphs [0002] to [0003], [0013] to [0014] and [0032] to [0040], and the examples, etc. & US 6391899 A</p> <p>Document 2: JP 2002-281999 A (Kazuhiro IGARASHI), 02 October 2002, test 2</p> <p>Document 3: JP 2002-181820 A (Ikagaku Co., Ltd.), 26 June 2002, claims and paragraph [0002]</p> <p>Claims 1, 2, 4 and 5</p> <p>Document 1 indicates that polyamine oxidases and polyamines such as spermine or spermidine are associated with cerebrovascular accidents and cerebral ischemia.</p> <p>Thus, it would have been easy for a person skilled in the art to conceive of using measured polyamine levels and/or measured polyamine oxidase levels in order to screen patients and diagnose cerebrovascular accidents or the like.</p> <p>Consequently, claims 1, 2, 4 and 5 do not involve an inventive step.</p>

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>Claims 3 and 6</p> <p>Document 2 indicates that polyamine oxidases produce 3-aminopropanal from polyamines, whereafter the 3-aminopropanal immediately forms acrolein.</p> <p>Meanwhile, document 1 indicates that the polyamine oxidases generate 3-aminopropanal from the polyamines, and thus it is thought that acrolein will also be present when polyamine oxidases and polyamines are present.</p> <p>As a result, it would have been easy for a person skilled in the art to conceive of using acrolein as an indicator for detecting cerebrovascular accidents and/or cerebral ischemia.</p> <p>Consequently, claims 3 and 6 do not involve an inventive step.</p> <p>Furthermore, document 3 indicates that it is possible to detect arteriosclerosis by detecting for anti-acrolein antibodies, and also indicates that arteriosclerosis is a primary cause of cerebral infarctions and the like.</p> <p>As a result, it would have been easy for a person skilled in the art to conceive of detecting cerebral infarctions by detecting for acrolein.</p> <p>Consequently, claims 3 and 6 do not involve an inventive step.</p> <p>Claims 7 and 8</p> <p>In addition, document 1 indicates that the polyamine oxidase activity is elevated for a number of hours subsequent to the onset of ischemia, and also indicates that it is possible to confirm whether the activity of the polyamine oxidase is elevated before it is possible to confirm the presence of a characteristic</p>

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
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pattern within a diagnostic image of the head.

Consequently, claims 7 and 8 do not involve an
inventive step.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The inventions set forth in the present application use the polyamine level or the aldehyde level as an indicator for detecting cerebrovascular accidents or the like. However, the description only describes the relationship between cerebrovascular accidents and FDP-Lys, and thus there is not considered to be sufficient support for the inventions set forth in the present application (furthermore, there is insufficient support for the claim that is possible to determine the acrolein level by measuring the FDP-Lys level).
2. Claims 7 and 8 of the present application indicate that statistically significant changes in the activity and/or the level of the polyamine oxidases will occur before it becomes possible to detect anything in a diagnostic image of the head. However, the description only presents one example in which this assertion holds true, and thus there is not considered to be sufficient support for the inventions set forth in claims 7 and 8.